IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

URL PHARMA, INC., MUTUAL PHARMACEUTICAL COMPANY, INC., and UNITED RESEARCH LABORATORIES, INC., Plaintiffs, v. RECKITT BENCKISER INC., Defendant.	Case No. 15-cv-505 **HON. PETRESE B. TUCKER** **JURY TRIAL DEMANDED**

URL PHARMA, INC., MUTUAL PHARMACEUTICAL COMPANY, INC. AND UNITED RESEARCH LABORATORIES, INC.'S RESPONSE IN OPPOSITION TO RECKITT BENCKISER INC.'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT

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I. INTRODUCTION[1]

The issue here is whether Mutual has sufficiently alleged Reckitt's leveraging of its patent rights and the pharmaceutical regulatory scheme to obtain a procompetitive settlement of patent litigation and its subsequent repudiation of the settlement ("the Agreement" or "Settlement Agreement") to illegally extend its monopoly over extended-release guaifenesin ("ERG") products constitutes monopolization or attempted monopolization.

The Agreement included a promise by Mutual not to challenge Reckitt's Mucinex® monopoly by selling Mutual's alleged non-infringing ERG products for at least five (5) years. To secure Mutual's promise, Reckitt agreed, *inter alia*, if a third party launched a generic version of a Mucinex® dosage, Mutual could purchase Reckitt's corresponding dosage for resale as a generic. After Reckitt enjoyed nearly seven (7) years of unchallenged monopoly, a third party launched a 600 mg ERG product and Mutual made a demand for the promised ERG supply. Reckitt did not supply Mutual. Reckitt repudiated the Agreement without justification and for the sole purpose of extending its monopoly in the ERG market.

Reckitt's repudiation of the Agreement is a scheme to exclude competition and charge inflated prices to achieve higher profits. An inherent problem with Reckitt's repudiation is it forces or attempts to force a large reverse payment on Mutual as compensation for keeping Mutual off the market. Reckitt has no legal right to pay Mutual for its market absence and to reap the reward of its continuing monopoly. Reckitt's conduct is anticompetitive behavior not permitted by the antitrust laws.

[1] Reckitt fails to adhere to this Court's Policies and Procedures by filing a dispositive motion without notifying Plaintiffs or seeking a settlement conference. *See* Hon. Petrese B. Tucker, POLICIES AND PROCEDURES 4 (available at: https://www.paed.uscourts.gov/documents/procedures/tucpol.pdf).

Reckitt's unsupportable factual and legal attacks on Mutual's well-pled complaint are evidence of Reckitt's long-standing policy of delay and subterfuge to illegally extending its ERG monopoly as long as possible. Mutual alleges a plausible claim that Reckitt's conduct is in violation of the antitrust laws. Mutual also satisfies the pleading requirements for breach of contract, specific performance, and declaratory judgment counts. Mutual's well-pled claims should not be dismissed and discovery should commence so Mutual can enter the market and relieve the public of the harm caused by Reckitt's illegal exclusionary conduct.

II. FACTUAL BACKGROUND

A. The Regulatory Context For Mutual's Claims

A basic description of the pharmaceutical industry, and in particular the regulatory context surrounding Mutual's claims, is necessary to assess the sufficiency of Mutual's pleadings.[2]

The sale of ERG products requires prior FDA approval. For a new drug, the FDA first approves a New Drug Application ("NDA") containing data demonstrating the safety and efficacy of the drug. *See King Drug Co. of Florence v. Cephalon, Inc.*, No. 2:06-CV-1797, 2015 WL 356913, at *1 (E.D. Pa. Jan. 28, 2015). Prior to 1984, an application to sell a generic version of the drug needed to repeat the testing submitted in the NDA. The testing was cost prohibitive for generic drug manufacturers, resulting in enduring monopolies on drugs and an enormous burden for consumers paying monopoly prices.

[2] An antitrust analysis is undertaken with reference to the relevant industry and any existing regulatory framework. *See* Dkt. No. 20-2, Reckitt's Mem. In Supp. Of Motion to Dismiss (*herein after "Mot.") at 10; *see also F.T.C. v. Actavis, Inc.*, 133 S.Ct. 2223, 2227-29, 2234. This is true in the highly regulated pharmaceutical market. *In re Suboxone Antitrust Litig.*, No. 13-MD-2445, 2014 WL 6792663, *10 (E.D. Pa. Dec. 3, 2014). ("This analysis must be undertaken with the somewhat unique characteristics of the pharmaceutical market in mind."); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 421-22 (D. Del. 2006) (same).

The Hatch-Waxman Act was enacted in 1984 to make it easier for generic manufacturers to bring generic drugs to market. *See id.* at *1-*2. For the first time, manufacturers could submit an Abbreviated New Drug Application ("ANDA") and rely on the safety and efficacy testing of the drug described in the NDA. The abbreviated process makes it economically feasible for generic manufacturers to bring cheaper generic drugs to market.

The Hatch-Waxman Act also includes provisions encouraging generic companies to challenge patents covering branded drugs. *Id.* at *2. The Act simultaneously protects patentees against approval of ANDAs describing products that might infringe their patents. A manufacturer submitting an ANDA gives notice to patentees and the NDA holder if it is challenging patents as either invalid or not infringed. The patentee can choose to sue the ANDA applicant for patent infringement and the FDA is then precluded from approving the ANDA for 30 months irrespective of actual infringement by the ANDA holder. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

The potential for anticompetitive conduct is unintentionally built into the regulatory scheme because it allows branded drug companies to leverage their patents to delay market entry of even non-infringing products. Branded drug companies – and to a lesser extent generic drug companies – have sometimes leveraged the patent litigation provisions of the Hatch-Waxman Act to engage in an array of anticompetitive practices. For example, a common concern is branded companies bringing sham patent infringement suits to obtain the Act's automatic 30-month stay of FDA approval, thereby delaying inevitable generic entry. *See, e.g.*, *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 376 (S.D.N.Y. 2002). In the most litigated scheme, brand companies settle Hatch-Waxman litigation by paying generic competitors to stay off the market. *See F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). The payments are called "reverse payments"

and in some cases have been in excess of hundreds of millions of dollars. Large and unexplained reverse payments can be anticompetitive. *See id.* at 2237.

The opportunity for parties to engage in anticompetitive behavior in the pharmaceutical market has been deemed substantial enough that Congress requires settlement agreements arising from Hatch-Waxman litigation be submitted to the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC") within ten (10) business days of execution. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2461-63 (2003). The FTC examines settlement agreements to weigh their anticompetitive potential against procompetitive justifications and the policy favoring settlement of disputes. The FTC rejects settlements where the brand company pays the generic company to stay off the market. *See generally Actavis*, 133 S. Ct. 2223.

B. The Nature Of The Dispute

Reckitt has a patent covering bilayered ERG products it sells under the Mucinex® brand. In 2006, Mutual filed an ANDA seeking approval to sell generic versions of Mucinex®. In response, and pursuant to the Hatch-Waxman Act, Reckitt sued Mutual for patent infringement. Mutual alleged its product did not infringe Reckitt's patent and, further, that Reckitt's patent infringement suit was baseless because Reckitt had expressly disclaimed the product configuration Mutual was seeking to sell.[3]

In 2007, Reckitt and Mutual entered into a procompetitive settlement whereby Mutual was promised entry in the ERG market on certain conditions prior to the expiration of Reckitt's

[3] Mutual's disclaimer argument was affirmed by the Federal Circuit when the argument was presented in a later case Reckitt brought against another ANDA applicant. *Reckitt Benckiser Inc. v. Watson Labs., Inc.*, 430 F. App'x 871, 878 (Fed. Cir. 2011).

patent. The parties submitted the Agreement to the FTC and DOJ as required by the Hatch-Waxman Act and those agencies.

The Agreement provided in the event Mutual did not have FDA approval of its own product and a third party launched a generic version of a Mucinex® dosage, Mutual would have the option to purchase the corresponding dosage from Reckitt. The supplied product was to be manufactured using Reckitt's patented technology and pursuant to its NDA, a product known as an authorized generic ("Authorized Generic" or "AG"). Dkt. No. 1, Complaint (hereinafter "Compl.") at ¶ 21. Mutual would be licensed to resell the AG as a generic competitor for Mucinex®.

The Agreement was beneficial for Reckitt. As a publicly traded company, Reckitt had the ability to remove an overhanging uncertainty surrounding the near-term impact of generic entry and focus on growing its Mucinex® family of products. Furthermore, the Agreement had exclusionary power greater than Reckitt's patents because it secured a market monopoly immune from challenge by the only competitor seeking to sell a non-infringing product.[4]

Reckitt enjoyed its incontestable market monopoly for more than six-years, until a third party – Perrigo – launched a competing 600 mg ERG product. The launch triggered Mutual's right to purchase a 600 mg Authorized Generic, and Mutual made demand on Reckitt for the promised supply of ERG product. Reckitt, however, repudiated the Agreement, including the license granted Mutual. Reckitt claimed, *inter alia*, the Agreement it had negotiated and executed was too vague to be enforced.

In repudiating the Agreement, Reckitt knew two things: first, Perrigo's supply of competing product was limited, leaving virtually intact Reckitt's total monopoly; and second,

[4] The Agreement was procompetitive, however, because Mutual's ability to enter the market prior to expiry of Reckitt's patents was certain, as opposed to contingent on litigation success.

Mutual's decision to purchase an AG meant Mutual did not have FDA approval to sell its own product. Putting one and two together, Reckitt knew supplying Mutual with the AG meant competing in the ERG market against its own product, but delaying or outright refusing to sell the AG would allow Reckitt to extend its monopoly and monopoly profits. Refusing to sell made economic sense, because any damage award – or settlement – of a breach of contract claim would be less than the profits earned at monopoly prices. The damages award would also be immune from FTC and DOJ scrutiny as an illegal reverse payment.

Today, Reckitt continues to sell its Mucinex® products at monopoly prices and refuses to meet its supply obligations to Mutual. Mutual does not have an FDA-approved ANDA, and Mutual has been shut out of the ERG market notwithstanding its continued adherence to the Agreement. Mutual can submit new ANDAs to sell competing products, but that process will take years and force Mutual to once again run the gauntlet of Reckitt's patent enforcement strategies.

III. LEGAL STANDARD

A complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a), and provide a defendant with "fair notice of what the claim is and the grounds upon which it rests." *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007). A complaint need only contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). This standard is satisfied when a plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). Rule 12(b)(6) dismissals are historically disfavored in antitrust cases. *See Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738, 746 (1976) (cautioning that "dismissals prior to giving the plaintiff ample

opportunity for discovery should be granted very sparingly"). Accordingly, "[a]ntitrust complaints . . . are to be liberally construed [at the motion to dismiss] stage of the proceeding." *In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *7 (D.N.J. Aug. 28, 2009).

IV. MUTUAL'S COMPLAINT IS PLAUSIBLE ON ITS FACE

A. Elements Of Monopolization And Attempted Monopolization Claims

Section 2 of the Sherman Act "makes it unlawful to monopolize, or attempt to monopolize, … any part of the trade or commerce among the several States." *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 447 (2009) (internal quotations omitted). To establish liability for a monopolization claim, a plaintiff must demonstrate "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 480 (1992) (internal quotations omitted).

To prove attempted monopolization, a plaintiff must show "'(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.'" *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 893 (9th Cir. 2008) (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993)). The requirements of the claims are similar, "differing primarily in the requisite intent and the necessary level of monopoly power." *Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1202 (9th Cir. 1997) (internal citations omitted).

B. Mutual Has Properly Pled Its Monopolization And Attempted Monopolization Claims.

1. Reckitt Possesses Monopoly Power In The Relevant ERG Product Market

The first element of a Section 2 monopolization claim is monopoly power in a relevant market. Monopoly power can be proven through "direct evidence of supracompetitive prices and restricted output" or inferred through "the structure and composition of the relevant market." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) (internal citations omitted); *see also In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013). In defining the relevant market, "whether there are additional products that are 'reasonably' interchangeable with [the alleged product] involves questions of fact not properly addressed in a . . . motion to dismiss." *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000); *see also Eastman Kodak*, 504 U.S. at 482.

Reckitt appears to concede market power in the ERG market. *See* Mot. at 7 ("RB holds the Mucinex ERG Patents and, thus, has a lawful patent monopoly over its product."). Even if Reckitt does not concede market power, Mutual has pled monopoly power by showing direct evidence of supracompetitive pricing. For example, Mutual has alleged that after Perrigo's limited entry into the ERG market, Reckitt discounted its corresponding product 16%. Compl. at ¶ 34. Such "discounting of Mucinex® in response to competition demonstrates that its ability to charge monopoly prices was dependent on its exclusion of generic competitors from the market." *Id.*[5] Reckitt does not address or acknowledge these allegations.

Reckitt argues Mutual fails to define a relevant market because "[s]pecific factual allegations are necessary to justify the counterintuitive inference that a product is so unique that

[5] Mutual also alleges Reckitt was able to sell its ERG products at a premium compared to immediate release guaifenesin products, demonstrating ERG was a separate market, or at the least a submarket, within the guaifensin therapeutic category. Compl. at ¶¶ 32-33.

it has no actual or potential competitors." *See* Mot. at 13. But Reckitt simply ignores the "specific factual allegations" in Mutual's complaint, which other courts have explicitly recognized as sufficient for pleading relevant market.

A comparison to *SmithKline Corp. v. Eli Lilly & Co.* – a case selectively quoted by Reckitt, but not analyzed for its true holding – is instructive. 575 F.2d 1056 (3d Cir. 1978). In *SmithKline*, the Third Circuit affirmed the district court findings that the relevant product market – "the market where there is true economic rivalry because of product similarity" – was composed of a ***specific subclass*** of antibiotics known as cephalosporins. *Id.* at 1065. In so holding, the court explained that cephalosporins "possess sufficiently unique features" indicating lack of interchangeability with other antibiotics. *Id.* at 1064; *see also Bayer Schera Pharma AG v. Sandoz, Inc.*, No. 08-03710, 2010 WL 1222012, at *5 (S.D.N.Y. Mar. 29, 2010) (suggesting product uniqueness can be determined when products "contain different amounts of the active ingredients or different forms of the active ingredients").

As in *Smithkline*, Mutual alleges ERG is sufficiently unique to comprise its own relevant market. Indeed, it is evident from the complaint there is no "cross-elasticity of demand" between ERG and other guaifenesin products or cold-remedy products:

> "Guaifenesin is the ***only FDA-approved expectorant*** consumers can purchase over the counter to ***thin bronchial secretions*** . . . . " Compl. at ¶ 30 (emphasis added). *Compare Smithkline*, 575 F.2d at 1064 (finding cephalosporins unique because they "possess sufficiently unique features").
>
> "Other available cold remedies, including cough remedies, work differently to help mask symptoms of cold and flu." Compl. at ¶ 31. *Compare Smithkline*, 575 F.2d at 1064 (finding cephalosporins unique because they show "significant differences . . . in the area[] of effectiveness" against alternative medicines).
>
> "For example, many cold and flu remedies contain decongestants which can cause increases in blood pressure and are therefore not recommend for individuals suffering from hypertension." Compl. at ¶ 31. *Compare Smithkline*, 575 F.2d at 1064 (finding cephalosporins unique because they show "fewer undesirable side

effects" and can be used in patient populations typically adverse to alternative forms of treatment).

Reckitt ignores cases specifically defining the relevant market as a single branded product and its generic. *See, e.g.*, *In re Nexium*, 968 F. Supp. 2d at 389 (holding "[t]he fact that other drugs may be used to treat heartburn and related conditions is immaterial to the present inquiry" and accepting, as pled, a product market consisting of Nexium and its generic equivalents); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla. 2005) (relevant market was brand and generic terazosin hydrochloride). Only by glossing over Mutual's factual allegations and ignoring relevant law is Reckitt able to spin an argument for insufficient pleadings. But, as recognized time and again, "[t]he proper market definition in this case can be determined only after a factual inquiry into the 'commercial realities' faced by consumers." *Eastman Kodak*, 504 U.S. at 482 (internal quotations omitted).

2. Reckitt Extended Its Monopoly Through Exclusionary Conduct.

a. The Applicable Rule Of Reason Framework

The second element of a Section 2 monopolization claim examines whether the defendant acquired or maintained monopoly power through anticompetitive exclusionary conduct. *Eastman Kodak*, 504 U.S. at 480. The rule of reason analysis applies to determine the anticompetitive nature of the alleged conduct, in particular where the issues presented lie at the intersection between the patent and antitrust laws. *See, e.g.*, *Actavis*, 133 S. Ct. at 2238.

The rule of reason framework applied to this element was described in *United States v. Microsoft Corp.*, 253 F.3d 34, 58-59 (D.C. Cir. 2001), and has been applied in the context of the pharmaceutical industry in this district and elsewhere. *See Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 422 (D. Del. 2006); *In re Suboxone*, 2014 WL 6792663. The framework for determining anticompetitive conduct is three-part and involves shifting burdens:

> The plaintiff must demonstrate that the defendant's conduct had an anticompetitive effect. If the plaintiff establishes an anticompetitive effect, then the monopolist may proffer a precompetitive justification for its conduct – "a nonpretextual claim that its conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal." If the monopolist succeeds, then the plaintiff must rebut that justification or demonstrate that the anticompetitive harm of the conduct outweighs its precompetitive effect.

New York v. Actavis, 2014 WL7015198, *38 (S.D.N.Y. 2014) (internal quotations and citations omitted). The inquiry is inherently factual, and inappropriate for adjudication on a motion to dismiss. *See Eastman Kodak*, 504 U.S. at 482; *In re Cardizem*, 105 F. Supp. 2d at 680. Furthermore, the plaintiff's initial burden on pleading is met when it alleges actual anticompetitive effects. *See e.g., Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 74 (3d Cir. 2010) (enunciating rule of reason standards in summary judgment context); *Glaberson v. Comcast Corp.*, No. 03-6604, 2006 WL 3762028, at *12 (E.D. Pa. Dec. 19, 2006) (denying motion to dismiss Sherman § 1 claims where, under the rule of reason, plaintiffs sufficiently alleged anti-competitive harm in the relevant market).

b. Mutual Has Alleged An Anticompetitive Effect Of Reckitt's Conduct And Has Pled Antitrust Injury

Antitrust effect may be demonstrated when the challenged conduct is shown to affect the prices or quantity of goods or services. *Tunis Bros. Co. v. Ford Motor Co.*, 952 F.2d 715, 728 (3d Cir. 1991) ("An antitrust plaintiff must prove that challenged conduct affected the prices, quantity or quality of goods or services.") (internal quotations and citations omitted). The inquiry is highly factual, and the existence of antitrust injury is not historically resolved through motions to dismiss. *See Eastman Kodak*, 504 U.S. at 482; *Trustees of Rex Hosp.*, 425 U.S. 746; *In re Neurontin*, 2009 WL 2751029, at *7. Mutual alleges – and Reckitt does not dispute – Reckitt's repudiation of the Settlement Agreement has prevented Mutual from entering the ERG market. Compl. at ¶ 27. Mutual further alleges its entry into the ERG market would have increased

supply and reduced prices. *Id.* Mutual pleads direct evidence showing the introduction of even a limited quantity of a competing 600 mg ERG product in the market resulted in lower prices for consumers and forced Reckitt to reduce price on its corresponding Mucinex® product. Compl. at ¶ 34. Mutual, therefore, alleges Reckitt's exclusion of Mutual from the ERG market has had an anticompetitive effect and caused Mutual anticompetitive injury. Compl. at ¶¶ 27, 34, and 36-40.

Reckitt attacks the sufficiency of Mutual's pleadings by arguing Mutual has not demonstrated anticompetitive market effect or injury to Mutual arising from illegal conduct.[6] Specifically, Reckitt alleges the existence of its patent gives it the unfettered right to exclude Mutual. Mot. at 16. Reckitt further alleges that injury to Mutual, specifically, cannot be an antitrust injury because Mutual was precluded from legally entering the ERG market and at most Mutual has a breach of contract claim. Reckitt's argument strains credulity and exemplifies the fact Reckitt is impermissibly expanding the scope of its patent monopoly. *See* Section IV, *infra*.

In 2007, Reckitt leveraged its patent through the regulatory process to induce Mutual to keep its alleged non-infringing ERG product out of the market. The cost to Reckitt to secure and expand its monopoly was the grant of a patent license to Mutual allowing Mutual to sell Reckitt's patented product prior to patent expiry. A patent license exhausts a patentee's right to exclude the licensee from the market. *Anton/Bauer, Inc. v. Pag Ltd.*, 329 F.3d 1343, 1350 (Fed. Cir. 2003) ("[I]t is well settled that all or part of a patentee's right to exclude others form making, using, or selling a patented invention may be waived by granting a license, which may be express or implied."). The patent license made it *legal* for Mutual to enter the ERG market.

Having accepted the benefit of the bargain for nearly seven years, Reckitt's unjustified repudiation of the license for the sole purpose of extending its monopoly is not a right conferred

[6] Reckitt's anticompetitive effect and anticompetitive injury arguments are identically premised on the alleged legality of Reckitt's conduct based on its patents.

by the patent grant. *Int'l Wood Processors v. Power Dry, Inc.*, 792 F.2d 416, 429 (4th Cir. 1986) ("Surely a patentee does not contemplate that as part of his reward he will be able to grant and revoke licenses at will, despite contractual obligation to the contrary, whenever his marketing strategy changes.") (finding patentee's breach of a license agreement was a violation of the Sherman Act).[7] Reckitt's motion leaves no doubt in repudiating the Settlement Agreement, it is reasserting its patent rights against Mutual. Mot. at 16-17. As such, the anticompetitive effect plausibly articulated in Mutual's complaint is neither a function of Reckitt's justifiable use of its patent nor a consequence of Mutual's being legally precluded from entering the market.[8]

C. Reckitt's Justifications For Repudiating The Agreement Are Misguided and Pretextual

Reckitt relies on two false premises to support its principal argument in support of dismissal. First, Reckitt improperly argues Mutual has failed to allege Reckitt's conduct is outside the scope of the rights conferred by its patent. Mot. at 7. "Absent such allegations," Reckitt argues, "[it] cannot be deemed to be lawfully monopolizing or attempting to monopolize a market for Mucinex ERG where it holds a lawful patent monopoly." *Id.* This argument is irrelevant because Mutual clearly pleads Reckitt's anticompetitive conduct "is an illegal extension of what were the proper limits of Reckitt's monopoly power pursuant to its patent rights." Compl. at ¶ 28. The purpose of this case is to probe the veracity of Mutual's claim.

Reckitt's second false premise flows from the first. Reckitt asserts "[t]he only exclusionary conduct alleged is a refusal to deal[.]" Mot. at 6 (emphasis in original). It is Reckitt, however, not Mutual who seeks to narrow the inquiry. Reckitt argues Mutual's failure to

[7] *Int'l Wood Processors*, 792 F.2d 416, demonstrates Reckitt's repudiation of the license in the context of these facts gives rise to a plausible Section 2 claim. As such, the injury to Mutual does not sound exclusively or narrowly in breach of contract, but in antitrust.

[8] As Mutual's complaint alleges anticompetitive effect and anticompetitive injury to Mutual, Mutual has standing to bring its Section 2 claims.

implicate Reckitt's patent means Mutual's complaint is nothing more than an allegation "that antitrust law confers a duty upon [Reckitt] to deal with Mutual." *Id.* at 7. The argument fails, at least because Mutual *does* allege Reckitt has exceeded the scope of the patent grant. Nevertheless, even if this were *just* a "duty to deal" case – a narrowly focused analysis not appropriate here – Mutual's complaint pleads a plausible cause of action.

Reckitt uses the Second Circuit's *Adderall* decision to cast Mutual's monopolization claim as a doomed "duty to deal" case. Mot. at 10-11. Although the Hatch-Waxman settlement agreement at issue in *Adderall* shares some factual similarity to the Agreement at issue here, the dismissal in *Adderall*, as described below, was brought about by plaintiffs' unusual litigation choice and the facts that Defendant Shire's alleged anticompetitive conduct *ended* its monopoly, *increased* competition and *reduced* prices. *See generally In re Adderall XR Antitrust Litig.*, 754 F.3d 128 (2d Cir. 2014).

First, Plaintiffs in *Adderall* explicitly disclaimed any importance of Shire's patent or the underlying Hatch-Waxman dispute to its claim. *Id.* at 133-34. In disclaiming the importance of the patent or the underlying context of the settlement, the *Adderall* plaintiffs stepped away from long-standing precedent applying traditional antitrust principles to cases involving the intersection between the patent and antitrust laws. *See, e.g., United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) (internal quotations omitted) ("It is . . . well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."); *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) (collecting cases in support of same); *In re Niaspan Antitrust Litig.*, No. 13-MD-2460, 2014 WL 4403848, at *12-13 (E.D. Pa. Sept. 5, 2014) (applying the rule of reason analysis to patent settlement in context of motion to dismiss);

Walker Process Equipment, Inc. v. Food Machinery & Chem. Corp., 382 U.S. 172, 174 (1965); *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 379-80 (1952); *Line Material*, 333 U.S. at 312 (1948). The approach was reaffirmed by the Supreme Court in *Actavis*, a decision contemporaneous to the briefing in *Adderall*.[9] *See Actavis*, 133 S.Ct. at 2231; *Adderall*, 754 F.3d at 132-33. The Court held to strike the balance between patents and antitrust law courts "must consider[] traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as … those related to patents." *Actavis*, 133 S.Ct. at 2231; *see also United States v. United States Gypsum Co.*, 333 U.S. 364, 390-391 (1948). The "balance" is struck, the Court instructed, by applying the traditional "rule of reason" analysis to alleged exclusionary conduct involving patents. *Actavis*, 133 S.Ct. at 2236.

Plaintiffs in *Adderall* chose not to pursue the rule of reason analysis mandated by the Supreme Court and argued the Second Circuit should assess Shire's conduct under the rubric applied in *Aspen Skiing*, the preeminent "duty to deal" decision of the Supreme Court. *Adderall*, 754 F.3d at 132. The Second Circuit recognized the analytical departure. The Second Circuit noted, repeatedly and disapprovingly, that plaintiffs had chosen the wrong theory of the case and had forsaken the Supreme Court's teaching in *Actavis.* As stated by the Court:

> As the *Actavis* decision illustrates, the tension between the objectives of preserving economic incentives to enhance competition while at the same time trying to contain the power a successful competitor acquires is heightened tremendously when the patent laws come into play. . . . <u>But any such tension is rendered irrelevant here by the plaintiffs theory of the case</u>.

Id. at 133 (emphasis added) (internal quotations and citations omitted). Reckitt attempts to force the same peculiar litigation choice on Mutual. *See* Mot. at 6 ("The <u>only</u> exclusionary conduct

[9] It is worth noting the *Actavis* decision overruled the Second Circuit's influential "scope of the patent" test for assessing anticompetitive settlement agreements in the Hatch-Waxman context.

alleged is a refusal to deal[.]") Reckitt's attempt should be disregarded. Mutual neither disclaims the importance of the patent, rejects the fact intensive rule of reason approach mandated by the Supreme Court nor advocates exclusively for the application of the "duty to deal" rubric. Notwithstanding these facts, *even if* the Court were to approach Mutual's complaint from the perspective of *Aspen Skiing*, *Adderall* does not mandate dismissal.[10]

In *Adderall*, Shire performed by supplying its product at the time promised, surrendering its monopoly to its direct competitors. *See* 754 F.3d at 130-31. The plaintiffs in *Adderall*, nevertheless, complained Shire's anticompetitive conduct was supplying only enough product to give the generics 50-60% of the market. *Id.* at 131. Keeping in mind the elements of a § 2 claim require pleading facts plausibly demonstrating the defendant created or extended a monopoly through exclusionary conduct, the *Adderall* Court's amused observation that "the plaintiffs' allegations amount[ed] to the self-defeating claim that Shire monopolized the market by ceding its monopoly." *Id.* at 135. The Court went on to note the plaintiffs were not even parties to the settlement agreement (they were purchasers of prescriptions drugs.) *Id.* The inference was the plaintiffs were neither in a good position to understand the rights and duties of Shire under the contract nor to assess the intent of Shire in supplying the quantities that destroyed its own monopoly. *Id.*

The facts here compel a different conclusion on a motion to dismiss. Reckitt has, *without justification*, repudiated the Settlement Agreement. As a party to the contract, Mutual is uniquely suited to understand the nature of the Agreement, the rights and duties described therein and to gauge the justification for Reckitt's conduct. Critically, Reckitt's conduct has blocked legitimate

[10] Reckitt doesn't analyze the "duty to deal" line of cases, but simply argues *Adderall* mandates dismissal. The posturing and facts here are distinct and *Adderall* does not support dismissal.

competition while Reckitt both continues to enjoy its monopoly over ERG products and charges monopoly prices facilitated by its repudiation. *Adderall* is therefore completely inapplicable.

Reckitt's subsidiary argument that a "breach of contract claim is not actionable under antitrust law", Mot. at 6, is without legal support and wrong. In *Int'l Wood Processors*, the Fourth Circuit affirmed the jury finding that repudiation of a patent license agreement was in violation of the antitrust laws and outside the scope of the patent grant. 792 F.2d at 429 (affirming a § 1 violation). As described in Section IV, *infra*, Reckitt's factual justifications for repudiating the Agreement cannot support Reckitt's motion to dismiss Mutual's monopolization claims. To the extent the Court does consider Reckitt's factual arguments, they are facially pretextual and serve to demonstrate the unjustified nature of Reckitt's breach.

D. Reckitt's Conduct Is An End Run Around The Prohibition Against Large Reverse Payments

Settlement Agreements involving the use of reverse payments to keep generic competitors off the market are subject to antitrust scrutiny under the rule of reason test. *See generally Actavis*, 133 S.Ct. 2223. The Hatch-Waxman Act requires litigants to submit settlements of patent litigation arising from the Act to the FTC and DOJ for antitrust review. The FTC and DOJ can object to those agreements deemed anticompetitive attempts by brand companies to pay for market exclusivity. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2461-63 (2003).

The Settlement Agreement at issue here was a procompetitive compromise that survived FTC and DOJ scrutiny. In particular, the Agreement did not involve a "reverse payment" requiring Reckitt to pay Mutual to stay off the market. Reckitt's repudiation eliminates the procompetitive justifications for the Agreement – early market entry for Mutual – and tips the scale firmly to the side of anticompetitive exclusionary conduct. In particular, now that FTC and

DOJ review is complete, Reckitt is repudiating the Agreement and electing to pay Mutual a large reverse payment – either in the form of settlement or a breach of contract damage award – to stay off the market. *See* Compl. at ¶ 6, 40. Reckitt's conduct is nothing more than an innovative way of paying Mutual to stay off the market, but still an exclusionary scheme in violation of the antitrust laws.

E. Mutual Has Sufficiently Pled Specific Intent For Attempted Monopolization

Mutual's allegations of attempted monopolization involve an inquiry into Reckitt's intent. *See Cascade*, 515 F.3d at 893 (internal quotation omitted). Examination of intent is factual and sufficiently pled by Mutual. *See, e.g.*, Compl. at ¶¶ 26 ("Reckitt understands that if it had met its obligation . . . it would have lost its ability to freely extract monopoly profits . . . ."), ¶ 27 ("In refusing to supply Mutual, Reckitt has improperly extended its monopoly . . . ."). In response, Reckitt offers only factual disputes highlighting the dispute is real and not to be dismissed. *See* Mot. at 8-9 (arguing the Agreement is "inconsistent with the conduct of an alleged monopolist," yet glossing over that it repudiated the contract and now claims it is unenforceable). Thus Mutual has sufficiently pled Reckitt's intent to monopolize.

V. RECKITT'S MOTION TO DISMISS THE CONTRACT CLAIMS SHOULD BE DENIED

Reckitt improperly attempts to dismiss Mutual's breach of contract claims by asking this Court to accept as true each of Reckitt's factual assertions – all of which are contradicted by the black letter of the agreement – and to declare the settlement agreement unenforceable. The Court should reject this blatant attempt to obtain a decision on the merits through a motion to dismiss.

A. Mutual Is Estopped From Arguing The Unenforceability Of The Agreement.

The Agreement was executed on March 21, 2007. For nearly seven years Reckitt (i) enjoyed the benefits of the Agreement; (ii) took advantage of a competition-free ERG market to grow its Mucinex® brands both in sales and monopoly profits; and (iii) operated free from threat

of non-infringing generic entry from its licensee Mutual. But when time arrived for Mutual to collect the benefits of the Agreement, Reckitt saw the imminence of a lost monopoly. In response, Reckitt balked, tried to pay Mutual to stay off the market, and then repudiated the Agreement entirely.

Reckitt's unjustified repudiation of the Agreement constitutes an exclusionary expansion and reassertion of its exhausted patent rights and a second attempt to leverage the regulatory system to exclude Mutual. Its frivolous unenforceability argument arrives too late: after enjoying the benefit of the Agreement for nearly seven years, Reckitt is estopped from challenging the enforceability of the Settlement Agreement. *In re Ionosphere Clubs, Inc.*, 85 F.3d 992, 999-1000 (2d Cir. 1996) (a party is estopped from renouncing burdens of contract when it accepts benefits of same contract); *Marshall v. Pittsford Cent. Sch. Dist.*, 100 A.D.3d 1498, 1500 (N.Y. App. Div. 2012) (parties cannot accept benefits under a contract fairly made and at the same time question its validity).

B. Mutual Is Entitled to Specific Performance and Damages

Under New York contract law, Mutual must allege that an agreement existed, that it performed, that Reckitt breached and that Mutual was damaged. *See* Mot. at 17. Reckitt does not challenge Mutual's allegations it failed to supply Mutual with ERG. Instead, Reckitt asserts Mutual's complaint is deficient in failing to plead compliance with conditions entitling it to purchase ERG from Reckitt. *See id.* at 18-20. Reckitt also asserts the Agreement is unenforceable. *Id.* at 20-23. Both assertions rest on interpretations contrary to the pled facts. Further, Reckitt's "unenforceability" argument is plainly contrary to New York law.

1. Mutual Pled Compliance With The Settlement Agreement

Reckitt identifies three (3) conditions precedent it claims were required under the Agreement and Mutual failed to plead in its complaint. First, Reckitt claims Mutual did not

request the "correct" ERG product. *Id.* at 18-19. Second, Reckitt claims the request was deficient because it came from counsel acting on Mutual's behalf and not directly from Mutual. *Id.* at 19. Third, Reckitt claims the request was deficient because a third party was not "legally" and "continually" selling generic ERG and Mutual did not have a license to sell that third party's product. *Id.* at 19-20.[11] These disputes are purely factual.

As an initial matter, Reckitt fails to point the Court to Mutual's complaint where it pled each of the three (3) elements Reckitt alleges are absent. *See* Compl. at ¶¶ 22-24 (emphasis added). Reckitt's true argument is that ***it disagrees with the facts*** as set forth in the complaint. But at this stage, the Court must accept as true both Mutual's factual allegations of what transpired and its interpretation of the contract as based on the facts of record. Even more egregious, Reckitt's interpretations of the contract are contrary to the black letter of the Agreement and attempt to conceal other plausible – indeed ***more*** plausible – interpretations. *See Twombly*, 550 U.S. at 556 (a plaintiff need only set forth sufficient facts to state a plausible cause of action).

By way of example, Reckitt brings three factual disputes to the forefront. ***First***, Reckitt admits Mutual's notice identified the product it requested by name – "Adams' 600 mg guaifenesin tablets" – yet argues Mutual did not request product corresponding to a "Third Party Formulation." Mot. at 18-19 (emphasis in original). As pled, Mutual alleges it requested 600 mg ERG ***corresponding*** to the 600 mg ERG launched by Perrigo. Compl. at ¶¶ 22-24. ***Second***,

[11] Reckitt also argues Mutual was required to obtain FDA approval of its ANDA prior to obtaining the right to purchase ERG product. Mot. at 19-20. Mutual disagrees obtaining FDA approval is a condition precedent, and the contract makes it perfectly clear it is not: "WHEREAS, as a result of this Agreement, Mutual's ability to enter into competition with the Adams Guaifenesin Products is not subject to its ability to obtain approval of the Mutual Products[.]" Settlement Agreement, Dkt. No. 1-4 at 4. Mutual has no obligation to plead compliance with a non-existent, or at the very least disputed, contract provision. *See Ctr. For Concept Dev., Ltd. v. Godfrey*, No. 97-7910, 1998 WL 792157, at *2 (E.D. Pa. Nov. 10, 1998).

Reckitt argues "Mutual" never made the request. Yet, the notice clearly states: "Mutual elects to purchase Adams' 600 mg guaifenesin tablets for sale by Mutual." Dkt. No. 20-9 at 2.[12] ***Third***, Reckitt argues Perrigo was not lawfully selling its ERG product at the time Mutual provided notice, and therefore the right to purchase ERG was not ripe. Mot. at 19. But in the same breath, Reckitt admits Mutual alleged Perrigo had *lawfully* launched its product. *Id.* at 21. Reckitt simply disagrees with the facts pled in Mutual's complaint, and attempts to use those disagreements as grounds for dismissal. Without more than factual disputes, there are no bases for the Court to dismiss the Complaint.

Reckitt also takes issue with the plain reading of the contract stating Perrigo's ***launch*** of a generic ERG product triggers Mutual's right to purchase. *See* Settlement Agreement ¶ 5(b)(ii), Dkt. No. 1-4 at 12-13. Reckitt reads into the contract an unsupported requirement that Perrigo must be ***continuously*** supplying the market.[13] Mot. at 19 ("Mutual pleads that there were *lawful* sales but also avers that Perrigo withdrew its Generic ERG Product from the market (and only began selling again in November 2014")) (emphasis in original). The facts do not support such a reading. Indeed, Reckitt's interpretation cannot be true, given that the plain text of the Agreement reads Mutual may request Reckitt's ERG after a third party's "Launch Date". *See* Settlement Agreement ¶ 5(b)(ii), Dkt. No. 1-4 at 12-13. "Launch Date," as defined in the

[12] Reckitt cites to Fed. R. Civ. P. 17, which states that an "action must be prosecuted in the name of the real party in interest." Mot. at 19. Mutual is both a party to the Settlement Agreement and the Plaintiff here, thus Reckitt's argument is misguided.

[13] There is no dispute Perrigo launched product prior to Mutual's notice. *See* Mot. at 10. The quantity and price of product in the market at any given time is a factual issue that will be the subject of discovery.

Agreement, means "date of ***first*** lawful commercial ***sale***." *See id.* at ¶ 5(b)(i), Dkt. No. 1-4 at 11 (emphasis added).[14]

Having failed to support its "conditions precedent" arguments, Reckitt next asserts Mutual failed to plead irreparable harm. Mot. at 17-18. Again, Reckitt ignores the plain reading of the contract – cited in Mutual's complaint – wherein the parties specifically agreed that, in the event of a breach, the non-breaching party would be entitled to specific performance as there is "no adequate remedy at law." Compl. at ¶ 36. Mutual also pled the product Reckitt is obligated to supply Mutual is unique. *Id.* Under New York law, non-breaching purchasers are entitled to specific performance of supply contracts where the goods being supplied are unique and supply has been refused. N.Y. U.C.C. § 2-716(1). Reckitt's motion to dismiss Mutual's request for specific performance should, therefore, be denied.

2. The Settlement Agreement Is Enforceable Under The Law

Reckitt argues the Agreement is unenforceable under New York law because "material terms" are missing, yet it provides no basis for this Court to declare as much on a motion to dismiss. *See* Mot. at 20-21. In the first instance, Mutual cannot address Reckitt's one sentence argument that the Agreement is an unenforceable "agreement to agree" without calling on the Court to entertain the underlying merits of Mutual's claims. Although Reckitt asserts the Agreement leaves open "the most basic and material terms, including quantity, and even clear

[14] Reckitt also argues Mutual should have requested, ***from Reckitt***, "the generic extended-release guaifenesin ***made by Perrigo***." Mot. at 18 (emphasis added). Reckitt's position is devoid of any merit. The Agreement explicitly states "[t]he tablets supplied by [Reckitt] shall be … manufactured using [Reckitt's] . . . bilayered technology." *See* Settlement Agreement ¶ 6(a), Dkt. No. 1-4 at 13. Perrigo's product does ***not*** use Reckitt's bilayered technology, which is why it does not infringe Reckitt's patents. Reckitt's exclusionary position is contrary to the black letter of the Agreement. *See also* Bulk Supply Agreement ¶ 5.1(b), Dkt. No. 1-4 at 39 ("…[E]ach Product Manufactured under this Agreement … shall have been Manufactured in accordance with [Reckitt's] NDA …")

identification of the product being purchased," it leaves to the Court to parse through the Agreement on its own. *See id.* at 21. Mutual has no burden to rebut a proposition Reckitt itself fails to support.[15] As such, the Court should reject Reckitt's pure attorney argument that the Agreement is an unenforceable "agreement to agree."

Reckitt additionally requests the Court declare the Settlement Agreement unenforceable under the New York Uniform Commercial Code. The attendant argument is a mere recitation of hornbook contract law with no analysis of the operative instrument. Mot. at 21-22. Presumably, Reckitt argues that material terms are missing and thus the Statute of Frauds is not satisfied. But yet again, the Court is left to parse through the Agreement with no direction. Such a task is unwarranted, though, as the quantity, price, ***and*** time and manner of delivery are set out in detail. *See* Bulk Supply Agreement, at §§ 2.1-2.5, 3.1 and Schedule B, Dkt. No. 1-4 at 34-36, 37, 49. Given Reckitt refuses to provide any insight on the contractual terms, the Court should not be forced to scrutinize the Agreement at such an early stage.

Finally, Reckitt "suggests" the Agreement could be a requirements contract, and requests dismissal because Mutual failed to plead the agreement is "exclusive."[16] Mot. at 22-23. Reckitt has both the law and facts wrong. Pursuant to New York law, the buyer must agree to purchase his requirements exclusively from the seller. *Embedded Moments, Inc. v. Int'l Silver Co.*, 648 F. Supp. 187, 192 (E.D.N.Y. 1986). There is no corresponding requirement the ***seller*** agree to exclusively supply the buyer. As pled, Reckitt is the only source of the unique goods Mutual is

[15] Although, Mutual directs the Court to the Complaint, which states, "Mutual provided Reckitt written notice that . . . . it was electing to purchase from Reckitt 600 mg ERG product." Compl. at ¶ 24. Furthermore, the Bulk Supply Agreement states "Mutual shall give [Reckitt] Mutual's good faith estimate of Mutual's projected requirements of such Product [i.e., Reckitt's 600 mg ERG] for delivery . . . . .[E]ach such Forecast shall be binding . . . ." Dkt. No. 1-4 at 35.

[16] Reckitt's refusal to take a position as to as to what the contract is demonstrates declaring the Agreement unenforceable or dismissing the complaint at this early stage is unfounded.

entitled to purchase and, as such, the Agreement mandates Mutual purchase ***exclusively*** from Reckitt. *See* Compl. at ¶ 39. Further, Reckitt concedes it is the exclusive supplier of bilayered ERG 600 mg tablets based on its patents. *See* Mot. at 7. This concession demonstrates the exclusive nature of the Settlement Agreement, and Reckitt's motion to dismiss on the basis of Mutual's purported failure to allege "exclusivity" must fail.

VI. THE COURT HAS JURISDICTION OVER MUTUAL'S DECLARATORY JUDGMENT COUNT

The Court applies a three factor test for ripeness. *See Pittsburgh Mack Sales & Serv., Inc. v. Int'l Union of Operating Engineers, Local Union No. 66*, 580 F.3d 185, 190-91 (3d Cir. 2009) (internal quotations omitted). Reckitt's ripeness argument is aimed at ERG formulations other than the 600 mg formulation, Mot. at 24, but it fails to mention a determination of Reckitt's obligations to the supply 600 mg ERG is necessarily a determination of its obligations to supply the other formulations. There are no sets of facts pertaining to non-600 mg ERG, hypothetical or otherwise, that could affect the Court's interpretation of the contract language.

Mutual's claim is also ripe because Reckitt repudiated its obligation to supply ***any*** formulation. Mutual's claim is not, therefore, contingent on a hypothetical. *Pittsburgh,* 580 F.3d at 191 ("Pittsburgh Mack's claim is not based on a contingency . . . ."). Third parties have submitted ANDAs seeking to sell other ERG formulations. Compl. at ¶ 80. It is expected those parties will receive approval to sell and Reckitt's obligation to supply will be triggered. Determining the issue is both practical and useful as Mutual will know whether it must plan for its impending market entry with respect to those formulations. *Pittsburgh,* 580 F.3d at 192 ("[D]etermining the issue is practical and useful because at the conclusion [Plaintiff] will know whether or not it can proceed with . . . suit against [Defendant].").

VII. CONCLUSION

For the reasons stated herein, Mutual respectfully requests the Court deny Defendant's motion to dismiss. In the event the Court grants all or part of Reckitt's motion Mutual respectfully requests the Court grant it leave to amend the complaint. In the event the Court dismisses the antitrust claim, Mutual requests the Court retain supplemental jurisdiction pending any appeal of the Court's dismissal.

Dated: April 23, 2015

Respectfully submitted,

/s/ *Stephen P. Benson*
Stephen P. Benson (pro hac vice)
Daniel P. Shapiro (pro hac vice)
Kristina Y. Liu (pro hac vice)
Matthew M. Holub (pro hac vice)
KATTEN MUCHIN ROSENMAN LLP
525 W. Monroe St. Suite 1900
Chicago, Illinois 60661
312-902-5200

John J. Grogan
Howard I. Langer
LANGER GROGAN & DIVER, PC
1717 Arch Street, Suite 4130
Philadelphia, PA 19103
215-320-5662
Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on April 23, 2015, I caused true and correct copies of URL PHARMA, INC., MUTUAL PHARMACEUTICAL COMPANY, INC. AND UNITED RESEARCH LABORATORIES, INC.'S RESPONSE IN OPPOSITION TO RECKITT BENCKISER INC.'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT to be served upon all counsel of record via the Court's ECF System.

/s/ *Matthew M. Holub*
Matthew M. Holub